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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

WARREN GENERAL HOSPITAL, on behalf of itself and all others similarly situated  Plaintiff,	Civil Action No
v. AMGEN, INC.	COMPLAINT AND JURY DEMAND
Defendant.	: : x

Plaintiff Warren General Hospital, upon knowledge with respect to its own acts and upon information and belief with respect to all other matters, alleges by way of Complaint against Defendant Amgen, Inc. ("Amgen"):

### **SUMMARY OF CLAIMS**

1. This antitrust action, brought under Section 1 of the Sherman Act and Section 3 of the Clayton Act, involves an anti-competitive tying scheme implemented by Amgen in the marketing and sales of its Red Blood Cell Growth Factor ("RBCGF") and White Blood Cell Growth Factor ("WBCGF") drugs. The scheme improperly used Amgen's market power in the WBCGF market to impair competition in the RBCGF market, by forcing Plaintiff and class members to make substantial purchases of Amgen's more-expensive RBCGF drug, rather than

the cheaper competing RBCGF drug, in order to avoid losing money on their purchases of Amgen's dominant WBCGF drugs. Both WBCGF and RBCGF drugs are needed to treat cancer patients, but for different purposes. The purpose of Amgen's scheme was to eliminate competition in the market for sales of RBCGF drugs. The scheme was successful and resulted in less competition, less physician and patient choice and an increased expense to Plaintiff and the proposed class as well as to the public health system.

- 2. Amgen and Ortho Biotech Products, L.P. ("Ortho") sell competing versions of RBCGF drugs. Amgen's version is called Aranesp and Ortho's version is called Procrit. Both of these RBCGF drugs compete head-to-head in a two-player market. Annual combined sales of these two products exceeded \$8 billion in 2005.
- Amgen also sells Neulasta and Neupogen, which are WBCGF drugs with a 3. combined 98% market share of sales to direct purchasers such as hospitals and oncology clinics. Thus, Amgen has a monopoly in the market for WBCGF drugs.
- During the class period, January 1, 2003 to the present, Amgen's sales of Aranesp 4 substantially increased as the result of Amgen's continuing illegal tying scheme, which penalized Plaintiff and the class on their purchases of Amgen's monopoly WBCGF drugs when those purchasers did not also purchase significant volumes of Amgen's Aranesp, instead of its competitor's Procrit. Simply put, because Nuelasta and Neupogen were dominant drugs (having an almost complete monopoly), Amgen had no economic incentive to offer purchasers any incentives to purchase these drugs by themselves. Thus, the only reason Amgen provided such incentives was to illegally force Plaintiff and the class to purchase Aranesp, in order to give Amgen's RBCGF drug a competitive advantage over Procrit. Amgen's "competitive advantage" resulted in damages to Plaintiff and the class in the form of the increased prices they had to pay

- for 1) Aranesp over Procrit, and/or 2) the bundle of Aranesp and the WBCGF drugs they purchased over the bundle of RBCGF and WBCGF drugs they would have purchased absent the illegal tying scheme.
- 5. During the course of the class period, Amgen's continuing tying scheme became considerably more coercive. Amgen began imposing steeper pricing penalties on Amgen's monopoly WBCGF drugs when purchasers such as hospitals, doctors or oncology clinics did not purchase larger percentages (up to 90%) of their RBCGF drugs from Amgen. In fact, over time Amgen required Plaintiff and the class to continue to purchase larger amounts of Aranesp just to receive the same level of rebates they had been receiving, which level allowed them to avoid losing money on their purchases of WBCGF drugs.
- 6. Amgen's continuing tying scheme coerced purchasers into purchasing virtually all of their RBCGF drug requirements from Amgen, because without the rebates from those RBCGF purchases, purchasers such as doctors, oncology clinics and hospitals would lose money on every administration of Amgen's monopoly WBCGF drugs, i.e., the cost of buying Neupogen and Neulasta (absent the contractual rebates) exceeded the amount of reimbursement such purchasers received from Medicare and other health care payors, which represented a significant portion of revenue to Plaintiff and the class. Thus, it was commercially unreasonable for Plaintiff and the class to purchase Amgen's monopoly WBCGF drugs without the rebates they received pursuant to their coerced RBCGF purchases, which purchasers could only achieve when they purchased virtually all of their RBCGF drug requirements from Amgen.
- 7. Defendant's conduct constituted an illegal tying scheme in violation of Section 1 of the Sherman Act and Section 3 of the Clayton Act under either a per se or rule of reason analysis. As the result of Amgen improperly leveraging its monopoly power in the WBCGF

drug market, Amgen's tying scheme left purchasers with no economic alternative but to purchase virtually all of their needed RBCGF drugs from Amgen. Thus, Plaintiff and the proposed class were damaged in two ways: 1) they were forced to pay more for Aranesp than they would have paid for Procrit, and/or 2) they paid more for the bundle of Aranesp and the WBCGF drugs than they would have paid for the bundle of RBCGF and WBCGF drugs.

- 8. WBCGF and RBCGF drugs are distinct and separate products used for wholly different purposes, and are not at all interchangeable substitutes. Thus, RBCGF and WBCGF drugs constitute separate product markets. During the class period, annual sales in the United States of the drugs affected by Amgen's scheme, namely Aranesp, Procrit, Neulasta and Neupogen, all numbered in the hundreds of millions of dollars, certainly a substantial amount of interstate commerce.
- 9. Moreover, but for Amgen's improper tying arrangement, Ortho would have been able to compete in the RBCGF market as it did prior to the illegal tying scheme, and Plaintiff and the class would have benefited from such competition in the form of lower prices. Thus, denying direct purchasers such as hospitals, doctors and oncology clinics, and ultimately patients, access to competition is not in the public interest and has harmed consumers. Plaintiff and the proposed class should not have had to face such economic coercion, *i.e.*, forcing physicians who treat cancer patients to select a drug solely because it is the only economically viable way to gain access to another essential drug for their patients, is not, by any measure, in the public interest.
- 10. For these reasons and to remedy the injuries that have been caused by Amgen's anticompetitive conduct, Plaintiff and the proposed class seek treble damages.

### **JURISDICTION AND VENUE**

- 11. This complaint is filed under Section 4 of the Clayton Act, 15 U.S.C. § 15, for damages resulting from violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 3 of the Clayton Act, 15 U.S.C. § 14. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202.
- 12. Defendant transacts business and is found in this district. Substantial interstate trade and commerce involved and affected by the alleged violations of antitrust law occurs within this district. The acts complained of have had substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22 and 26.

### THE PARTIES

- 13. Plaintiff Warren General Hospital is a Pennsylvania not-for-profit corporation with its principal place of business located in Warren, Pennsylvania. Plaintiff is an acute care hospital servicing the community in and about Warren, Pennsylvania. During the class period, Plaintiff purchased Aranesp, Neulasta and Neupogen directly from Amgen, pursuant to a contract between Amgen and Plaintiff. The contract was negotiated at Warren Hospital between Plaintiff and an Amgen representative, who continued to service the account. The contract also required Amgen to pay the rebated dollars directly to Plaintiff, which it did. As a result of the alleged antitrust violations, Plaintiff and members of the proposed class have been injured in their business or property.
- 14. Defendant Amgen is a corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta, to direct purchasers such as hospitals, doctors and oncology clinics.

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## **FACTUAL ALLEGATIONS**

# A. Procrit and Aranesp are the Only Competitors in the Sale of RBCGF Drugs to Plaintiff and the Class.

- 15. Severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.
- Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.
- Agreement ("PLA") executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments, except for patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen.
- 18. In 1991, the FDA approved the marketing of Procrit for the treatment of persons who developed anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the drug zidovudine, (3) chronic kidney diseases in pre-dialysis patients, or for (4) anemic patients scheduled to undergo elective, non-cardiac, nonvascular surgery.

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- 19. Following the FDA ruling, Amgen decided to sell its version of epoeitin alfa for all purposes under the name of Aranesp. Amgen re-formulated the drug by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa in the PLA. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.
- 20. Given the scope of the patents, during the class period Ortho and Amgen were the only two competitors in the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales of Procrit and Aranesp exceeded \$8 billion in 2005.

### B. Amgen Has a Monopoly on the Sale WBCGF Drugs.

- 21. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a potentially life-threatening white blood cell deficiency. Neutropenia is a side effect of chemotherapy which can compromise a patient's immune system. The disease affects many patients undergoing chemotherapy, as well as individuals suffering from a number of other diseases.
- Amgen's initial WBCGF drug. In 2002, Amgen introduced the more powerful Neulasta, which has been modified so that one injection of Neulasta is roughly equal to 7 injections of Neupogen.
- 23. The only other WBCGF drug sold during the class period is Leukine, which was distributed by Berlex Laboratories.
- 24. Throughout the class period, Amgen has dominated the market for WBCGF drugs, which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to direct purchasers such as hospitals, doctors and oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product

has been on the market for many years, it has only a very small share of WBCGF sales. Its small market share is due to fact that, unlike Amgen's WBCGF drugs, which are administered by subcutaneous injection, Leukine is generally administered intravenously, a longer and more costly process.

#### C. Amgen Sought to Eliminate Competition in the RBCGF Drug Market by Leveraging its WBCGF Drug Monopoly.

- **Amgen Begins Bundled Pricing on Aranesp** 1. and its WBCGF Monopoly Drugs.
- 25. Plaintiff and the proposed class purchase and administer both RBCGF and WBCGF drugs to patients. Given Amgen's monopoly on WBCGF drugs, Plaintiff and the proposed class must buy their WBCGF drugs, particularly Neulasta, from Amgen.
- 26. This was not lost on Amgen as it developed its illegal tying scheme for Aranesp. Starting in 2002, when Amgen received approval to market Aranesp and Neulasta, Amgen's strategy was to make it commercially unreasonable for Plaintiff and the proposed class to purchase its dominant WBCGF drugs without also purchasing substantial amounts of Aranesp, a product that had competition. The volume requirements in Amgen's tying scheme for its RBCGF and WBCGF drugs were, in fact, market share requirements designed to force Plaintiff and the proposed class into purchasing Aranesp, which is more expensive per dose than Procrit.
- 27. While Amgen used different rebate percentages for different class members, the overarching continuing scheme was to leverage Amgen's monopoly power in the WBCGF market to coerce Plaintiff and all class members into purchasing Aranesp rather than Procrit. Amgen locked purchasers into its illegal tying scheme by various means, including its Amgen Portfolio Contract ("APC"), and its Momentum Rebate, Momentum II and Enhanced Momentum II Contracts.

28. Throughout the Class Period, Amgen was aware of and understood the reimbursement structure which regulated payments to class members from Medicare and other payors. Amgen used this knowledge to create its scheme, pursuant to which it set purchasing requirements for its RBCGF and/or WBCGF drugs. Amgen's requirements corresponded to rebates that class members would receive for purchases of RBCGF and WBCGF drugs if the requirements were met. Amgen set such levels so that Plaintiff and class members would lose money on purchases of the WBCGF drugs unless they met the Aranesp purchase requirements and received the corresponding rebates.

### 2. The Early 2004 Amgen Contract

- At that time, Amgen began offering substantial "rebates" to Plaintiff and the proposed class on the condition that they reach combined volume requirements for Amgen's RBCGF and WBCGF drugs.
- 30. Amgen's pricing was generally broken into three groups large, medium and small accounts based on the amount of RBCGF and WBCGF drugs purchased. Each account was given dollar volume usage targets that, if reached, allowed the purchaser to earn a specified level of rebate. Amgen's contracts contained dollar volume amounts for Aranesp, which corresponded to market share targets, that Plaintiff and the class were required to purchase in order to obtain sufficient rebates for Nuelasta and Neupogen, such that Plaintiff and the class would be reimbursed enough to avoid losing money on those drugs. Put another way, if Plaintiff and the class did not purchase enough Aranesp, their rebates on Nuelasta and Nuepogen would be so low, that the reimbursement they would receive for those drugs from Medicare and other

payors would be less than their costs, thus causing them to lose money. As stated above, Amgen set its targets based on its knowledge of the relevant reimbursement schedules.

- 31. For example, from 2003 through early 2004, Amgen's Momentum Rebate agreement required Plaintiff to purchase Aranesp for 60% of its total RBCGF purchases in order to be able to obtain a 20% rebate for Aranesp and a 4% rebate for Nuelasta and Neupogen. Then in early 2004, Amgen modified the purchasing requirement (through the Momentum II agreement) so that Plaintiff needed to make Aranesp purchases totaling over 69.5% of its total RBCGF purchases in order to obtain rebates of 17% for Aranesp (a reduction of 3% from the prior obligation) and 6% for Neupogen and 8% for Neulasta. Absent achieving the Aranesp purchase requirements, and thereby obtaining the highest possible rebates from Amgen, Plaintiff and the class would be reimbursed by Medicare less then the cost of the WBCGF drugs. Amgen knew this, based on its knowledge of the Medicare reimbursement schedule.
- 32. Similarly, under Amgen's APCs in effect in the first half of 2004, a large account which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, if an account purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen, it would have received significantly greater rebates a 25% rebate on Aranesp purchases and a 25% rebate on Amgen WBCGF drug purchases. Absent those rebates provided pursuant to the illegal tying scheme, Amgen provided only a minimal rebate or discount that it knew would result in the purchaser losing money on WBCGF purchases, considering the reimbursement mechanism then in place.

#### 3. **The Late 2004 Amgen Contracts**

- 33. Recognizing that it still had not fully maximized its leverage of its monopoly WBCGF products, later in 2004, Amgen modified its sales and marketing program, i.e., tying scheme, to require even larger Aranesp purchase requirements. For example, Amgen instituted the Enhanced Momentum II contract which required Plaintiff and the class to purchase over 80% of their RBCGF drugs from Amgen in return for a rebate of 21.5% for Aranesp and 15% for Nuelasta and Neupogen.
- 34. Amgen similarly modified its APCs to maximize the amounts of Aranesp that class members had to purchase to obtain the rebate levels necessary to avoid losing money per administration of its dominant WBCGF drugs. As a result, Amgen's modified APCs imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified combined dollar volume targets and corresponding higher rebate levels.
- 35. Amgen's actions forced class members to purchase greater amounts of Aranesp (which was more expensive per dose then the competing drug Procrit) in order to obtain the rebate levels on Amgen's monopoly WBCGF drugs necessary to avoid losing money on their utilization. In addition, by increasing the potential rebates, Amgen was further able to penalize anyone that failed to meet the dollar volume requirements. With these modifications to its program, Amgen continued to use its leverage on its monopoly WBCGF drugs to coerce the purchase of substantial amounts of Aranesp.
- For example, pursuant to the modification to Amgen's APCs in late 2004, a large 36. purchaser who obtained roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, if it purchased roughly 85% of its combined volume of

RBCGF and WBCGF drugs from Amgen, it would receive a 30% rebate on its Aranesp purchases and a 25% rebate on its WBCGF drug purchases.

- 37. These modifications to the continuing scheme forced direct purchasers such as hospitals, doctors and oncology clinics to buy less Procrit (less expensive per dose than Aranesp) and more Aranesp in order to attain the higher rebates, which were essential to avoid losing money on the reimbursement for Amgen's WBCGF drugs.
- 38. During the course of the Class Period, Amgen's illegal tying scheme caused the market share for Amgen's Aranesp to substantially grow and cause Procrit's market share to correspondingly fall.
- 39. This significant shift in relative market share was not attributable to Amgen improving its product in any way or to any other means of legitimate competition, but to direct purchasers such as hospitals, doctors and oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order to achieve the large rebates on their purchases of the WBCGF drugs they had to buy from Amgen, which rebates allowed them to avoid losing money on each dose.
- 40. The effect of Amgen's coercive tying arrangement is evidenced by comparing market shares of Procrit and Aranesp in sales to direct purchasers such as hospitals, doctors and oncology clinics with the market shares in sales to retail drug stores where Amgen has not introduced this tying arrangement. In 2005, in the retail drug store market, where Procrit and Aranesp competed head to head without Amgen using its leverage from its WBCGF monopoly to interfere, Procrit had approximately 70% of the market. In the market for sales to direct purchasers such as hospitals, doctors and oncology clinics, Procrit's market share decreased due to the tying scheme and is significantly lower than 70%.

41. In contrast, for purchasers who were subject to Amgen's illegal tying scheme, sales of Aranesp in the United States increased in 2004 by 56%.

## 4. Amgen's 2005 Pricing Scheme

- 42. Having gained a 65% share of sales to direct purchasers such as hospitals, doctors and oncology clinics by tying WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen then further tightened its squeeze on this market. Effective October 1, 2005, Amgen's continuing tying scheme became even more coercive.
- 43. Amgen continued to set for purchasers a series of dollar volume targets for their combined Amgen purchases of RBCGF and WBCGF drugs, as illustrated below for a large account. The higher the gross purchases of Aranesp, the higher the level of rebates a class member could achieve:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%

44. However, in this example, to avoid losing money on its purchases of Amgen's dominant WBCGF drugs, a purchaser had to reach level 6, which required that it buy at least

75% of its total RBCGF product purchases from Amgen, artificially increasing Aranesp's market share to 75%.

- A higher initial dollar volume threshold for Aranesp was only the start of this increasingly coercive tying scheme. The true purpose of the revised pricing scheme was to further boost Aranesp's market share to more than 75% of the RBCGF purchases of the proposed class. Under the modified program, for a purchaser to receive the same aggregate value it had been receiving while performing under the pre-October 1, 2005 scenario (described above), it then had to reach a higher dollar volume, *i.e.*, market share, in its purchases of Aranesp. For example, in late 2005, the top Aranesp rebate was 26%, 4% less than under the previous Amgen combined rebate of 30%. However, the purchaser could earn back the additional 4% by increasing its Aranesp share to 90%. Thus, the revised pricing scheme was intended to and did raise the Aranesp share of the RBCGF market well above where it would have been but for Amgen's use of its monopoly position in the WBCGF market.
- 46. The revised pricing scheme also reduced the highest Neulasta rebate from 25% to 21%. As with the Aranesp rebates, a purchaser could earn back the 4% on Neulasta if it reached the higher threshold for Amgen's Aranesp (up to 90%) as well.
- 47. The October 2005 modifications to Amgen's continuing tying scheme placed limits on the amount of the WBCGF drugs that could be considered for purposes of determining rebate levels on combined RBCGF-WBCGF purchases. Conversely, there were no such caps on Aranesp purchases, which further coerced direct purchasers such as hospitals, doctors and oncology clinics into purchasing all or substantially all of their RBCGF drugs from Amgen, even though it was more expensive per dose than its competing drug.

- 48. A purchaser that did not meet its Aranesp volume requirement would receive a lower rebate or no rebate on Neulasta, which would result in that purchaser losing money on its Neulasta purchases. For Plaintiff and class members, that lost money was significant.
- 49. As a result of Amgen's illegal scheme, sales of Aranesp in the United States increased in 2005 by 37% and correspondingly, Ortho's sales of Procrit decreased. Amgen's illegal scheme was designed, and succeeded, in coercing Plaintiff and class members to purchase Aranesp instead of Procrit in order to remain profitable on their overall use of Aranesp, Neupogen and Neulasta across all payers.
- 50. Ortho competed vigorously with Amgen in the RBCGF market towards the beginning of the class period. However, Ortho eventually was unable to effectively compete because of Amgen's ability and willingness to continue to improperly leverage its WBCGF monopoly in the form of greater rebates. As long as Amgen had monopoly power in the WBCGF market, and used it in setting the rebates available for WBCGF drugs based on sales of Aranesp, Ortho would have had to price Procrit below cost in order to match Amgen's rebates on its sales of Aranesp and its WBCGF drugs.
- 51. But for Amgen's improper tying arrangement, Ortho would have been able to compete in the RBCGF market as it did prior to the illegal tying scheme, and Plaintiff and the class would have benefited from such competition in the form of lower prices. Thus, Plaintiff and the class were injured by having to pay higher prices for Aranesp than they would have paid for Procrit, had Amgen not impaired and foreclosed competition in the RBCGF market. If Plaintiff and the class did not meet Amgen's purchase requirements for Aranesp they were also damaged because they would receive below cost reimbursement for Amgen's WBCGF drugs.

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## D. Amgen's Pricing Schemes Injured Plaintiff and the Proposed Class.

- 52. Failing to achieve a dollar volume on Aranesp purchases roughly equivalent to a 75% market share had severe economic consequences on direct purchasers such as hospitals, doctors and oncology clinics. Those severe consequences stemmed from Amgen's willingness to exploit its monopoly in the WBCGF drug market; as WBCGF drugs were necessary to treat neutropenia, class members had no choice but to carry Neulasta.
- Amgen's continuing tying scheme caused anti-competitive effects in the RBCGF market. Amgen economically coerced direct purchasers such as hospitals, doctors and oncology clinics into purchasing their RBCGF product, Aranesp, as a condition for receiving substantial rebates on the WBCGF drugs that they had to purchase from Amgen, due to Amgen's monopoly in that market. Unless they purchased significant amounts of Amgen's RBCGF drugs, they would not qualify for the massive rebates provided on Amgen's dominant WBCGF drugs, which would result in them losing money on their purchases of WBCGF drugs. Moreover, if they bought virtually all of their RBCGF and WBCGF drugs from Amgen, they were given even higher rebates. The only economically viable option for Plaintiff and class members was to purchase all or nearly all of their RBCGF drugs from Amgen, even though Aranesp had a higher list price and acquisition price, per dose, than its competitor Procrit.
- 54. Thus, Amgen illegally used its monopoly power in the WBCGF drug market to force Plaintiff and the class to purchase Aranesp, and caused Plaintiff and the proposed class to pay a higher price for 1) RBCGF drugs per dose individually, and 2) the bundle of WBCGF and RBCGF drugs combined, than they would have but for Amgen's illegal activity. Amgen's illegal tying scheme also damaged Plaintiff and the class in the form of the higher prices they had to pay for RBCGF drugs due to Amgen's illegal efforts to prevent Ortho from being able to

effectively compete in the RBCGF market, in that Ortho would have had to price Procrit below cost to match Amgen's monopoly-assisted prices.

- 55. One specific example of how Amgen's illegal tying scheme coerced purchasers into buying Aranesp involved reimbursements to oncology clinics from Medicare. Medicare patients make up roughly 40% of the patient population treated by class members. As such, the economics of treating this patient group is a major consideration. Without the Neulasta rebates (up to 25%), under the government's then-current reimbursement formula, a class member would have had to pay Amgen significantly more on each treatment of Neulasta for a Medicare patient than the class member would have received in reimbursement from the government and patients. Amgen knew this and acted to exploit it.
- 56. On January 1, 2005, the federal government changed the formula for reimbursement for Medicare. The revised formula was based on the drugs' average selling price ("ASP" as it is known in the industry) plus 6%. Thus, if a class member bought a drug with an ASP of \$1,000, it would be reimbursed \$1,060. This reimbursement amount was static regardless of what the particular class member actually paid for the drug. The "plus 6%" was not intended to be profit, but to provide some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that required refrigeration, and bad debt from patients who did not make co-pays.
- As the term suggests, the ASP of a drug is an average based on the prices paid and discounts and rebates earned by all purchasers of such drug. Accordingly, a Medicare provider that did not, or could not, avail itself of all the rebates offered by a manufacturer could end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider would be reimbursed by the government (ASP + 6%). Where the price paid

exceeded the reimbursement amount, the provider actually suffered a loss on the acquisition of a particular drug.

- Unless the class member met Amgen's purchase requirements, and obtained the necessary rebates, this was precisely the situation it faced when it administered Neulasta, Amgen's dominant WBCGF product. The following example further illustrates: Neulasta's list price in the 4<sup>th</sup> quarter of 2005 was \$2,603. The Medicare reimbursement (*i.e.*, ASP plus 6%) per unit of Neulasta was \$2,078.66 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount was 20.17% or \$524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis under Medicare, a class member had to receive rebates and discounts equal to 20.17% below Amgen's list price. At that time, Amgen provided class members with just a 5% discount off list price and a 4% rebate if the class member failed to buy the requisite levels of Aranesp specified in their agreements. In other words, unless the class member met the Aranesp volume requirements, it would pay Amgen \$295.87 more per administration of Neulasta than they were being reimbursed by the government.
- 59. Amgen's illegal tying scheme, which had no legitimate business justification, had its intended effect, as evidenced by Amgen's financial statement for the third quarter of 2005, where it reported that Aranesp sales jumped 38 percent to \$840 million in that quarter.
- 60. Amgen's efforts to use its monopoly power in the WBCGF drug market to coerce direct purchasers such as hospitals, doctors and oncology clinics into buying substantial amounts of Aranesp caused those purchasers to substantially overpay for RBCGF drugs, 1) to avoid losing money on their essential purchases of Amgen's WBCGF drugs, as well as 2) causing overpayments on those purchasers' bundle of combined RBCGF and WBCGF drugs, and 3)

because Amgen's illegal tying scheme impaired and foreclosed Ortho's ability to effectively compete in the RBCGF market, which would have led to lower prices on RBCGF drugs, and finally 4) because Aranesp was more expensive per dose than Procrit.

of In 2005, Ortho filed a similar suit against Amgen in which it asserted that Amgen was illegally bundling sales of Aranesp with its WBCGF drugs. Ortho alleged that Amgen's tying arrangement required potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if those potential competitors were as efficient as Amgen. In this manner, Ortho alleged that Amgen's tying scheme was anti-competitive and violated the federal antitrust laws. In July 2008, Amgen resolved Ortho's antitrust claim by agreeing to pay Ortho \$200 million.

# E. There is No Legitimate Business Justification for Amgen's Tying Arrangement.

62. There is no legitimate business purpose or efficiency justification for Amgen's pricing scheme, which was employed for the sole purpose of eliminating competition in the sale of RBCGF drugs, thereby causing Plaintiff and the proposed class to pay more than they would have in a competitive market for both their RBCGF drugs and their combined bundle of RBCGF and WBCGF drugs.

### F. RBCGF Drugs Constitute a Relevant Product Market.

- 63. RBCGF drugs in the United States constitute a relevant product market separate and distinct from the WBCGF drug market. RBCGF drugs are unique products.
- 64. RBCGF drugs are sold throughout the United States with over \$4 billion in gross sales in 2005.
- 65. There are high barriers to entry in the sale of RBCGF drugs. Foremost among these barriers are Amgen's exclusive patent rights over epoetin alfa. A market entrant would also

have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) secure regulatory approval for its distribution in the United States, (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

#### G. WBCGF Drugs Constitute a Distinct and Separate Product Market.

- 66. WBCGF drugs in the United States constitute a relevant product market separate and distinct from the RBCGF drug market.
- 67. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.
- 68. Recognizing this, the Federal Trade Commission ("FTC") stated that "the research, development, manufacture and sale of Neutrophil Regeneration Products" (a.k.a. WBCGF drugs) is a "relevant line of commerce" in a Clayton Act 7 administrative Complaint filed against Amgen and the Immunex Corporation.
- 69. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter this market, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States; (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

### **CLASS ALLEGATIONS**

70. Plaintiff brings this action on behalf of itself and as representative of a Class of all direct purchasers who purchased Aranesp, Neupogen and Neulasta through an Amgen contract, such as an APC or Momentum Rebate, Momentum II or Enhanced Momentum II contract, which tied the rebates and/or discounts received on purchases of Neupogen and Neulasta to purchases of Aranesp during the period January 1, 2003 to the present. Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all government entities (except for government-sponsored employee benefit plans).

- 71. Plaintiff seeks class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.
- Thus, members of the Class are numerous and joinder is impracticable. The Class members are identifiable, *inter alia*, from information and records that are required by law to be maintained by Defendant.
- 73. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual members in part because Defendant has acted and refused to act on grounds generally applicable to the entire Class, thereby making appropriate equitable and declaratory relief with respect to the Class as a whole.
  - 74. Questions of law and fact common to the Class include, *inter alia*:
- a. Whether Defendant's conduct constitutes an illegal tying scheme under Section 1 of the Sherman Act and/or Section 3 of the Clayton Act;
- b. Whether Defendant abused its monopoly power in the WBCGF market in order to gain a competitive advantage in the RBCGF market;
- c. Whether Defendant's conduct had the effect of substantially lessening competition in the RBCGF market;

- d. Whether Defendant's unlawful conduct caused Plaintiff and the proposed class to pay more for their RBCGF drugs and/or their combined bundle of RBCGF and WBCGF drugs than they otherwise would have paid; and
- the appropriate measure of damages incurred by Plaintiff and the proposed e. class.
- Plaintiff will fairly and adequately protect and represent the interests of the 75. proposed class. The interests of the Plaintiff are not antagonistic to those of the proposed class. In addition, Plaintiff is represented by counsel, who are experienced and competent in the prosecution of complex class action, antitrust and consumer protection litigation.
- 76. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously. efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.
- 77. Plaintiff knows of no difficulty to be encountered by litigating this action that would preclude its maintenance as a class action.

### **CAUSES OF ACTION**

Document 1

### FIRST CLAIM FOR RELIEF

(Per Se and Rule of Reason Unlawful Tying under Section 1 of the Sherman Act, 15 U.S.C. § 1)

- 78. Plaintiff and the proposed class repeat and allege each and every allegation contained in paragraphs 1 through 76 with the same force and effect as if here set forth in full.
- 79. Amgen has engaged in an unlawful tying arrangement in unreasonable restraint of trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This illegal scheme coerced Plaintiff and the proposed class to purchase all or nearly all of their RBCGF drugs from Amgen.
- The product characteristics, uses and character of demand for RBCGF drugs --80. which are used to treat chemotherapy-induced anemia but not neutropenia -- are different from the product characteristics, uses and the character of demand for WBCGF drugs -- products that treat neutropenia, but not anemia. RBCGF and WBCGF drugs are distinct products that are used to treat different conditions and are not functionally interchangeable.
- 81. At all times relevant to this action, Amgen had substantial market power in the sale of WBCGF drugs, which it leveraged to force Plaintiff and the proposed class to purchase substantial amounts of Aranesp, which was more expensive per dose than its competing drug Procrit. That leverage also impaired and foreclosed competition in the RBCGF market by preventing Ortho from being able to effectively compete in that market, which competition would have benefited Plaintiff and the class in the form of lower prices on RBCGF drugs.
- A substantial amount of interstate commerce was affected by Amgen's tying 82. arrangement. The total sales of RBCGF drugs in 2005 exceeded \$4 billion in gross sales.

- Amgen's tying scheme forced Plaintiff and the proposed class to purchase all or 83. nearly all of their RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's scheme, which offered significant rebates for the purchase of Amgen's dominant WBCGF drugs if they were purchased in a package with large quantities of Aranesp, the only economically viable option for Plaintiff and the proposed class that needed WBCGF drugs was for them to purchase all or nearly all of their RBCGF drugs from Amgen.
- 84. Amgen's tying scheme had no legitimate business purpose. It achieved no legitimate efficiency benefits and had the anticompetitive effect of foreclosing competition in the sale of RBCGF drugs to Plaintiff and the proposed class.
- 85. Amgen's tying scheme adversely affected competition in the sale of RBCGF drugs to Plaintiff and the proposed class.
- 86. As a result of Amgen's violations of Section 1 of the Sherman Act, Plaintiff and the proposed class were injured in their business and property in an amount not presently known.

### SECOND CLAIM FOR RELIEF

# (Per Se and Rule of Reason Unlawful Tying under Section 3 of the Clayton Act, 15 U.S.C. § 14)

- 87. Plaintiff and the proposed class repeat and allege each and every allegation contained in paragraphs 1 through 76 with the same force and effect as if here set forth in full.
- 88. Amgen has engaged in an unlawful tying scheme in unreasonable restraint of trade and commerce, in violation of Section 3 of the Clayton Act, 15 U.S.C. § 14. This illegal scheme, which substantially lessened competition in the RBCGF market, coerced Plaintiff and the proposed class into purchasing all or nearly all of their RBCGF drugs from Amgen.
- 89. The product characteristics, uses and character of demand for RBCGF drugs -which are used to treat chemotherapy-induced anemia but not neutropenia -- are different from

the product characteristics, uses and the character of demand for WBCGF drugs -- which treat neutropenia, but not anemia. RBCGF and WBCGF drugs are distinct products that are used to treat different conditions and are not functionally interchangeable.

- 90. At all times relevant to this action, Amgen had substantial market power in the sale of WBCGF drugs, which it leveraged to force Plaintiff and the proposed class to purchase substantial amounts of Aranesp, which was more expensive per dose than its competing drug Procrit. That leverage also impaired and foreclosed competition in the RBCGF market by preventing Ortho from being able to effectively compete in that market, which competition would have benefited Plaintiff and the class in the form of lower prices on RBCGF drugs.
- 91. A substantial amount of interstate commerce was affected by Amgen's tying scheme. The total sales of RBCGF drugs in 2005 exceeded \$4 billion in gross sales.
- 92. Amgen's tying scheme forced Plaintiff and the proposed class to purchase all or nearly all of their RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's scheme, which offered significant rebates for the purchase of Amgen's dominant WBCGF drugs if they were purchased in a package with large quantities of Aranesp, the only economically viable option for Plaintiff and the proposed class that needed WBCGF drugs was for them to purchase all or nearly all of their RBCGF drugs from Amgen.
- 93. Amgen's tying scheme had no legitimate business purpose. It achieved no legitimate efficiency benefits and had the anticompetitive effect of foreclosing competition in the sale of RBCGF drugs to Plaintiff and the proposed class.
- 94. Amgen's tying scheme adversely affected and substantially lessened competition in the sale of RBCGF drugs to Plaintiff and the proposed class.

95. As a result of Amgen's violation of Section 3 of the Clayton Act, Plaintiff and the proposed class were injured in their business and property in an amount not presently known.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff and the proposed class respectfully request the following relief:

- A. That the Court certify the class pursuant to Rule 23 of the Federal Rules of Civil Procedure, certify Plaintiff as a class representative and designate its counsel as counsel for the class;
- B. Declare that Defendant's conduct constitutes a violation of Section 1 of the Sherman Act and Section 3 of the Clayton Act;
  - C. Granting Plaintiff and the proposed class damages as permitted by law;
- D. Granting Plaintiff and the proposed class their costs of prosecuting this action, together with interest and attorneys' fees, including such as allowed by statue; and
  - E. Granting such other relief as this Court may deem just and proper.

### **JURY DEMAND**

Plaintiff and the class hereby demand trial by jury of all issues properly triable thereby.

DATED: September 25, 2009

SPECTOR ROSEMAN KODFOFF & WILLIS, P.C.

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